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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,225	09/18/2000	Mary Lynne Hedley	08191/013001	4277

7590

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 12/07/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/664,225

Applicant(s)

HEDLEY ET AL.

Examiner

Dave Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-7, 10-14, 53-67, drawn to a hybrid DNA encoding multiple epitope(s) of tumor antigens, method of cancer treatment by DNA applications, classified in Class 536, 23.1, class 435, subclass 320.1, 458, class 514, subclass 44.

Group II. Claims 1-66, 68 and 69, drawn to a hybrid DNA encoding multiple epitope(s) of viral antigens, method of virally infected treatment by DNA applications, classified in Class 536, 23.1, class 435, subclass 320.1, 458, class 514, subclass 44.

Should Group I or Group II be elected, the Group claims will be examined to extent that the claims are embraced by the elected Group Invention.

The inventions are distinct, each from the other because of the following reasons:

The hybrid DNA of Group I and the hybrid DNA of group II comprise materially distinct product and generate different functions and effects, and each of which is not required for use with each other, and generates distinct biological functions and effect. In addition, the methods of using each of the Group claimed product constitutes patentably distinct inventions for the following reasons: inventions of Groups I and II comprise materially distinct steps: tumor antigenic epitope(s) vs. viral antigenic epitope(s), and are directed to distinct goals and effects. As a result, a search for prior art and consideration of patentability does not necessarily overlap with one another. Thus, the inventions of Groups I and II comprise materially steps, and generate different functions and effects.

Should Group I be elected, the claims of the elected Group are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named combination of each of the segments as recited in the claims (see claim 1,

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for example), wherein each of the segments must lists out a specifically number of epitopes and specifically named tumor antigen (see claim 67).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

Should Group II be elected, the claims of the elected Group are generic to a plurality of disclosed patentably distinct species comprising:

A specifically number of segments, and a specifically named combination of each of the segments as recited in the claims (see claim 1 or 37, for example), wherein each of the segments must lists out a specifically number of epitopes and a specifically named viral antigen and epitope corresponding to a specifically named viral elected strain (should HPV be elected), and further a specifically named Sequence of HPV (see claim 67). For example, even if the HPV species is elected, claims 42-47 and 52 embraces an enormous number of combination of HPV sequences from HPV strains for use in the making the elected hybrid DNA, and thus, a species restriction for a specifically named combination of epitopes, viral strain, and sequence ID NOS is required to negate an undue burden on the examiner to conduct prior art search and consideration for patentability.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

Should Group I or Group II be elected, and should the specifically named combination of each of the segments as recited in the claims be elected, the claims of the elected group are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named route of administration (see claims 63-65).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

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Should Group I or Group II be elected, and should the specifically named combination of each of the segments as recited in the claims be elected, and should a specifically named route of administration be elected, the claims of the elected group are generic to a plurality of disclosed patentably distinct species comprising:

A liposome or a microsphere.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, and/or because of the patentably distinct species as listed above, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Kimberly Davis, whose telephone number is **(703) 305-3015**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Clark*, may be reached at **(703) 305-4051**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen



**DAVE T. NGUYEN
PRIMARY EXAMINER**